14-1354-cv

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUSAN SIMON,

Plaintiff-Appellant,

v.

SMITH & NEPHEW, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of New York
(Hon. Paul A. Engelmayer)

BRIEF OF DEFENDANT-APPELLEE SMITH & NEPHEW, INC.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendant-Appellee Smith & Nephew, Inc. makes the following corporate disclosure statement:

Defendant-Appellee Smith & Nephew, Inc., is a wholly-owned, indirect subsidiary of Smith & Nephew plc. Smith & Nephew plc is a public entity incorporated under the laws of England and Wales. No publicly held corporation owns 10% or more of the securities of Smith & Nephew plc.

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STATEMENT OF ISSUES

1. Federal law preempts any state-law requirement "with respect to" a medical device "which is different from, or in addition to, any requirement" imposed by the Food and Drug Administration ("FDA") in granting the device pre-market approval. 21 U.S.C. § 360k(a). Each of Plaintiff's state-law claims concerned a metal liner that had received pre-market approval from the FDA. Plaintiff did not dispute that each of her claims would impose state-law safety and effectiveness requirements "different from, or in addition to," the federal requirements. Did the district court correctly dismiss each of Plaintiff's claims as preempted by federal law pursuant to *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)?

2. Did the district court correctly dismiss Plaintiff's claims for failure to state a plausible claim under *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), where Plaintiff failed to plead sufficient facts in support of the elements of each claim?

3. After Smith & Nephew's motion to dismiss the original complaint, the district court gave Plaintiff more than two months to prepare her amended complaint, but cautioned that "[n]o further opportunities to amend shall be granted." Did the district court abuse its discretion by declining to grant a second opportunity to amend after dismissing the amended complaint?

STATEMENT OF THE CASE

A. REGULATORY SCHEME APPLICABLE TO DEVICE AT ISSUE

This case concerns an FDA-approved medical device, the R3 metal liner. The applicable federal statute, the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq*., groups prescription medical devices into three classes. *Id.* § 360c(a)(1). Class III devices, which are at issue here, are the most closely-scrutinized by the FDA and must undergo a rigorous pre-market approval ("PMA") process before they can be marketed. *Riegel v. Medtronic, Inc*., 552 U.S. 312, 317-18 (2008). The FDA has promulgated numerous regulations setting out PMA requirements for Class III medical devices. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344-47 (2001). These regulations require that a PMA applicant produce comprehensive data from which the FDA can make a reasoned determination of the device's safety and effectiveness, including human clinical trials, design specifications, manufacturing processes, quality controls, and proposed labeling and advertising. 21 C.F.R. § 814.20; *see also Riegel*, 552 U.S. at 318 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(l)(A)). Pre-market approval represents the FDA's judgment that the device meets the applicable federal requirements for safety and effectiveness. *Riegel*, 552 U.S. at 323 (citing 21 U.S.C. § 360e(d)).

Even after it grants pre-market approval, the FDA maintains strict oversight of Class III devices. A manufacturer must receive supplemental PMA from the FDA before it may make any changes to the device relating to "design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness," and the FDA evaluates the proposed changes "under largely the same criteria as an initial application." *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)). "All procedures and actions that apply to [a PMA] application under [21 C.F.R. §] 814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change." 21 C.F.R. § 814.39(c)(1). Class III devices are also subject to post-approval reporting requirements, including informing the FDA of new studies, investigations, or incidents where the device caused or could have caused serious injury, and the FDA retains the authority to withdraw approval based upon such new information. *Riegel*, 552 U.S. at 319-20.

Congress has provided that the rigorous PMA review and approval process shall authoritatively determine the safety and effectiveness requirements applicable to each device. *Id.* at 316. In the MDA's express-preemption clause, Congress provided that state law may not impose any requirements "different from, or in addition to," those imposed by the FDA during the PMA process:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device

> intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The statute bars attempts to impose state-law requirements through common-law tort duties; lawsuits based on such preempted state-law duties are barred as well. *See Riegel*, 552 U.S. at 324-30.

B. REGULATORY HISTORY OF THE R3 METAL LINER

Plaintiff-Appellant Susan Simon ("Plaintiff") alleged in her Amended Complaint that Smith & Nephew's R3 metal liner used in her hip replacement surgery was defective, and that her purported injuries resulted from her use of the R3 metal liner together with the femoral head component of her hip replacement. *See, e.g.*, A-15 (¶ 30); A-19 (¶¶ 48-49); A-24 (¶ 62); A-26 (¶ 73). On appeal, Plaintiff repeatedly attempts to characterize this case as concerning a system called the "R3 Acetabular System." *See, e.g.*, Appellant's Brief ("App. Br.") at 11-14. As the district court explained, Plaintiff's allegations of harm all derive from the use of the metal liner—which was not part of the R3 Acetabular System when that system came to market. A-112-13.

The R3 metal liner that Plaintiff alleged caused her injury was approved by FDA as safe and effective through the PMA process. Smith & Nephew submitted the R3 metal liner for approval as a supplemental PMA, for use within one of

Smith & Nephew's hip resurfacing systems (the "BHR system"). FDA granted pre-market approval on November 13, 2008. *See* A-35-36 (FDA Premarket Approval Summary, PMA number P040033, Supplement number S006).[1] Since then, the R3 metal liner has received an additional supplemental PMA. *See* A-38-39 (FDA Premarket Approval Summary, PMA number P040033, Supplement number S013).[2]

Plaintiff noted in her Amended Complaint that the "R3 Acetabular System" came to market via a different process rather than through PMA. A-14-15 (¶¶ 21-24). The "510(k)" process allows FDA to clear a device for marketing without formal pre-market approval, if the device is substantially equivalent to a device already on the market. *Riegel*, 552 U.S. at 317 (citing 21 U.S.C. § 360c(f)(1)(A)). But at the time the R3 Acetabular System was cleared by FDA, in 2007, the system

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[1] *Available at* http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm. To access Supplemental PMA number S006 from this FDA website link, search for term "P040033" which provides a link to the PMA Summary for the original PMA device. Supplement number S006 can be accessed via the link at the bottom of this PMA Summary webpage, where the PMA supplements are listed. The district court took judicial notice of this document, and other FDA-approved documents, A-106 n.2; such documents "'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned,'" *Finn v. Barney*, 471 F. App'x 30, 32 (2d Cir. 2012) (quoting Fed. R. Evid. 201(b)(2)); *Bertini v. Smith & Nephew, Inc.*, No. 13 CIV. 79(BMC), 2014 WL 1028950, at *1 n.1 (E.D.N.Y. Mar. 17, 2014) (taking judicial notice of supplemental PMA approval and granting motion to dismiss).

[2] *Available at* http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm. *See supra* note 2 for instructions on how to access Supplement number S013 to PMA P040033.

did not include the metal liner component that Plaintiff alleges caused her injuries. A-106. The R3 metal liner component was later granted FDA approval via the supplemental PMA process. A-35-36; A-107; *see also* A-15 (¶ 26).

C. PROCEDURAL HISTORY

Plaintiff filed suit in the Supreme Court of the State of New York on February 15, 2013. Civil Docket No. 1:13-cv-01909-PAE, Docket Entry No. (hereinafter "Dkt.") 1, Ex. A. Smith & Nephew timely removed the case to the United States District Court for the Southern District of New York (Engelmayer, J.). Dkt. 1. The original complaint alleged that Plaintiff underwent a left total hip replacement, and that she was injured by two of the components of her hip replacement device – the R3 acetabular shell and the "anthology femoral component." Dkt. 1, Ex. A.

Smith & Nephew filed a motion to dismiss Plaintiff's original complaint, on the grounds that each cause of action was inadequately pleaded under federal pleading standards, on April 29, 2013. Dkt. 15. In response, Plaintiff asked for additional time to prepare an amended pleading. Dkts. 20, 22. The district court allowed Plaintiff multiple extensions of time to file an amended complaint, *id.*, but cautioned that "[n]o further opportunities to amend will be granted," Dkt. 18.

Plaintiff filed her Amended Complaint on July 9, 2013. A-11-30. This time, Plaintiff alleged that her physician had utilized the R3 metal liner and a femoral

head component, and that she had experienced pain, clicking, locking, and elevated serum chromium and cobalt levels due to the metal-on-metal interaction between the R3 metal liner and the femoral head component.[3] A-16 (¶¶ 34-36). The Amended Complaint asserted three causes of action: Strict Products Liability – Design Defect; Negligence; and Breach of Implied Warranty. A-19-30.

Smith & Nephew moved to dismiss the Amended Complaint on two separate and independent grounds: *first*, that each cause of action challenged the safety and effectiveness of the supplemental PMA-approved R3 metal liner and thus was expressly preempted by federal law; and *second*, that Plaintiff had failed to cure the pleading deficiencies in the original complaint. Dkt. 25.

The district court issued an Opinion & Order dismissing with prejudice all three causes of action on the bases of federal preemption and inadequate pleading. A-103-19. Taking judicial notice of the FDA approval documents for the R3 metal liner, A-106 at n.2, the court held that Plaintiff's claims as to the supplemental PMA-approved R3 metal liner were expressly preempted by federal law pursuant to *Riegel* and its progeny, A-111-19. The court also held that Plaintiff's claims as to any other component used in her surgery were inadequately pleaded under

[3] Although Plaintiff's original complaint alleged injury solely from Plaintiff's use of the "Smith & Nephew R3 three-hole hemispherical acetabular shell and the Smith & Nephew anthology femoral component," Dkt. 1, Ex. A, the Amended Complaint no longer alleged injury from these two specific device components.

federal pleading standards. *Id*. Because there were no adequately-pleaded, non-preempted claims in the Amended Complaint, the district court entered judgment. A-119.

Plaintiff filed a motion for reconsideration, Dkt. 41, which the district court unequivocally denied on March 26, 2014, A-120-30. Judge Engelmayer held that Plaintiff simply repeated arguments already considered and rejected by the court. A-124. He explained further that, even if reconsideration were warranted, Plaintiff had not adequately pleaded that Smith & Nephew designed or marketed the R3 metal liner to be used in conjunction with other components of her hip replacement system, in a manner other than that approved by the FDA. A-124-25. Furthermore, the district court held that, even if Plaintiff had adequately pleaded such a theory of liability, the claims still would be preempted because the preemption question is whether there are federal requirements particular to the R3 metal liner itself – not whether there are federal requirements particular to the *use* of the R3 metal liner. A-126-28. Finally, the district court denied as futile Plaintiff's requests for another amended pleading and for discovery prior to surviving the pleading stage. A-128-29. This appeal followed.

SUMMARY OF ARGUMENT

1. The district court correctly dismissed Plaintiff's claims as preempted by the MDA. The R3 metal liner, alleged to have caused Plaintiff's injuries, is a

Class III medical device, approved by the FDA pursuant to the rigorous PMA process as a supplement to an original PMA. In light of the stringent safety review process that Class III medical devices must undergo to obtain PMA approval, the MDA includes a provision expressly preempting state-law causes of action against manufacturers of Class III medical devices to the extent the causes of action impose requirements different from, or in addition to, the requirements of federal law. 21 U.S.C. § 360k(a). The United States Supreme Court has so held in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

The district court faithfully applied *Riegel*, holding that Plaintiff's claims as to the R3 metal liner sought to impose requirements different from, or in addition to, federal requirements and, therefore, dismissed the claims with prejudice. Furthermore, Plaintiff's physician's use of the PMA-approved R3 metal liner in a manner other than that approved by the FDA did not defeat express preemption.

Additionally, the district court correctly held that Plaintiff had failed to plead adequately any claim that Smith & Nephew designed or marketed the R3 metal liner to be used in a way other than that approved by the FDA, and that, regardless, such a claim would have been preempted by federal law, because the preemption analysis concerns federal requirements applicable the device itself, not to the use of the device. Moreover, even if Plaintiff had pleaded a violation of a federal requirement regarding marketing of the device, such a requirement would not have

been specific to the device at issue, and thus, such a claim would not have defeated preemption. Such a marketing claim also would have been impliedly preempted by federal law pursuant to 21 U.S.C. § 337(a) and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

Finally, Plaintiff did not plead any injury exclusively caused by the femoral head component (*i.e.*, without involvement of the PMA-protected R3 metal liner). As such, the district court correctly held that the R3 metal liner was the crux of each and every one of Plaintiff's claims and, therefore, dismissed the Amended Complaint with prejudice.

2. Although Plaintiff already had amended her original complaint in response to Smith & Nephew's first motion to dismiss, Plaintiff still failed to plead her claims in the Amended Complaint with the specificity required by Federal Rule of Civil Procedure 8(a) and the controlling United States Supreme Court case law, *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). The Amended Complaint was rife with conclusions but devoid of factual allegations to support Plaintiff's claims. Notably, Plaintiff did not adequately allege any "defect" in the PMA-approved R3 metal liner, the femoral component, or their combined use. The Supreme Court has made clear that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Thus, the district

court properly dismissed each and every cause of action in Plaintiff's Amended Complaint.

3. The district court did not abuse its discretion by denying Plaintiff's request for leave to file a further amended complaint. Because each and every one of Plaintiff's causes of action was preempted by federal law, and because Plaintiff's "proposed amendment would not address this deficiency," A-129, the district court properly denied as futile Plaintiff's request to replead once more. Likewise, on appeal, Plaintiff does not assert that she can escape preemption. Furthermore, the district court correctly held that it would have been futile to allow Plaintiff to file a second amended pleading because Plaintiff failed to show how she could correct her various pleading deficiencies.

ARGUMENT

Plaintiff's claims failed twice over. First, each of them attacked the safety and effectiveness of the R3 metal liner. But the FDA had already determined the R3 metal liner to be safe and effective through the PMA process, and Plaintiff may not pursue a common-law tort theory that seeks to impose different or additional safety and effectiveness requirements. Second, Plaintiff's conclusory allegations do not plead a plausible claim for relief. For either or both of these independent reasons, this Court should affirm the district court's judgment of dismissal.

I. The District Court Correctly Held That Each Of Plaintiff's Causes Of Action Was Preempted By Federal Law.

A. The Standard of Review.

This Court reviews *de novo* a district court's application of preemption principles. *See Goodspeed Airport LLC v. E. Haddam Inland Wetlands & Watercourses Comm'n*, 634 F.3d 206, 209 n.3 (2d Cir. 2011); *New York SMSA Ltd. P'ship v. Town of Clarkstown*, 612 F.3d 97, 103 (2d Cir. 2010).

B. As in *Riegel*, Each of Plaintiff's State-Law Claims Sought to Impose Requirements Different from or in Addition to Federal Requirements and Therefore Was Preempted.

This case calls for a straightforward application of binding Supreme Court precedent. In *Riegel*, the Supreme Court held that the MDA preempted New York common law claims similar to those at issue here, such as negligence, design defect, and breach of warranty. 552 U.S. 312 (2008). Congress has provided that state law may not impose any requirements "different from, or in addition to," those imposed by the FDA during the PMA process. *Id.* at 315 (citing 21 U.S.C. § 360k(a)). Riegel's common-law claims under New York law sought to impose requirements on a Class III medical device that were different from the requirements approved pursuant to the FDA's exacting and comprehensive PMA process.[4] *Id.* at 321-30. Those claims, therefore, were expressly preempted. *Id.*

[4] Like the R3 metal liner, the product at issue in *Riegel* was the subject of a supplemental PMA, as explained by this Court in the decision that the Supreme

The Supreme Court's application of the MDA's preemption clause is controlling here as well.

The *Riegel* Court held that the PMA process imposes device-specific requirements relating to safety and effectiveness: "Premarket approval . . . imposes 'requirements' under the MDA as we interpreted it in [*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)]. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—**it *is* federal safety review**." *Riegel*, 552 U.S. at 322-23 (emphasis added). After a device has gone through that federal review and met those federal requirements, a claim brought under state common law that challenges the device's safety and effectiveness seeks to impose a different or additional "requirement" and is specifically preempted by § 360k(a). *Id.* at 323-27. As the Court stated, "common-law liability is 'premised on the existence of a legal duty,' and a tort

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Court affirmed. *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 120 (2d Cir. 2006) ("[W]hen Medtronic wanted to revise the [device's] label, it submitted PMA supplements that requested approval for those revisions, and the FDA granted that approval. [T]here is no evidence that Medtronic ever made changes to the [device's] label other than through the PMA process."). As explained *supra*, "[a]ll procedures and actions that apply to a PMA application under [21 C.F.R. §] 814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change." 21 C.F.R. § 814.39(c)(1). There is absolutely no basis in *Riegel* or in the regulatory framework for distinguishing between initial and supplemental approvals through the PMA process.

judgment therefore establishes that the defendant has violated a state-law obligation." *Id.* at 324 (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 522 (1992) (plurality opinion)). Thus, the common-law duties were "requirements" within the meaning of the express preemption clause. *Id.* at 324-25.[5]

To prevail on her design defect claim, Plaintiff would have had to establish that the R3 metal liner should have been designed in a different way than that approved by the FDA. Therefore, Plaintiff's design defect claim sought to impose state-law requirements that were different from, or in addition to, FDA-imposed requirements. The district court correctly held that any such claim is preempted by federal law. A-114-15; *see, e.g.*, *Bertini v. Smith & Nephew, Inc.*, No. 13 CIV. 79 (BMC), 2014 WL 1028950, at *6 (E.D.N.Y. Mar. 17, 2014) ("[T]he design defect

[5] Since *Riegel*, "courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence *per se*." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (internal citations omitted) (listing cases), *aff'd*, 623 F.3d 1200 (8th Cir. 2010). This includes New York federal and state courts that have addressed the issue. *See, e.g.*, *Franzese v. St. Jude Med., Inc.*, No. 13-CV-3203(JS)(WDW), 2014 WL 2863087 (E.D.N.Y. June 23, 2014); *Burkett v. Smith & Nephew Gmbh*, No. CV 12-4895(LDW)(ARL), 2014 WL 1315315 (E.D.N.Y. Mar. 31, 2014); *Bertini v. Smith & Nephew, Inc.*, No. 13 CIV. 79 (BMC), 2014 WL 1028950 (E.D.N.Y. Mar. 17, 2014); *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197 (W.D.N.Y. 2011); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009); *Colombini v. Westchester Cnty. Health Care Corp.*, 899 N.Y.S.2d 58, 2009 N.Y. Misc. LEXIS 1907 (N.Y. Sup. Ct. 2009); *Lake v. Kardjian*, 22 Misc. 3d 960, 874 N.Y.S.2d 751 (N.Y. Sup. Ct. 2008).

claim rests on the alleged ability of Smith & Nephew to design an even safer device component. Therefore, this cause of action would impose additional requirements on defendant to design an even safer device component. Since these additional state requirements relate to the safety and effectiveness of defendant's devices, the portion of the design defect claim based on the R3 metal liner is preempted under the MDA."); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284, 288 (E.D.N.Y. 2009).

Additionally, the district court properly concluded that Plaintiff's purported breach of implied warranty claim and negligence claim hinged on her design-defect theory of liability. A-119. Plaintiff does not contest this determination in her appellate brief. Under New York law, the existence of a product defect underlies both causes of action, *see Lewis v. Abbott Labs.*, No. 08 Civ. 7480(SCR)(GAY), 2009 WL 2231701, at *4, *6 (S.D.N.Y. July 24, 2009), and a design defect is the only type of defect that Plaintiff attempted to plead. Accordingly, for the reasons discussed above, the district court properly ruled that Plaintiff's negligence and breach of implied warranty claims as to the R3 metal liner also were expressly preempted by federal law.

To the extent Plaintiff's additional causes of action possibly could be interpreted as based on a theory *other* than a purported design defect, her claims still would have been preempted. Indeed, for Plaintiff to prevail on her claim that

Smith & Nephew breached an implied warranty that the R3 metal liner was safe and effective, the district court would have had to find that the device was *not* safe and effective. Such a finding would contradict the FDA's determination of safety and effectiveness when it granted supplemental PMA. *See Bertini*, 2014 WL 1028950, at *11-12 (breach of implied warranty claims regarding PMA-approved device are preempted by the MDA); *Lake*, 22 Misc. 3d at 962, 874 N.Y.S.2d at 754 (same). Furthermore, an examination of Plaintiff's purported negligence allegations in the Amended Complaint shows that she merely sought to attack the PMA process itself. A-19-23. Accordingly, the district court properly dismissed these claims with prejudice.

C. Plaintiff Mischaracterizes the Device Components She Alleged Caused Her Purported Injury.

Plaintiff does not dispute the foregoing preemption principles, nor does she dispute that her claims seek to use state common law to impose different or additional requirements, within the meaning of the MDA's express preemption clause. Nor did she dispute these points below, as the district court noted. A-111. Instead, Plaintiff seeks to plead around preemption by mischaracterizing the regulatory history and the device components that she alleged caused her purported injury. She insists that her surgery involved an "R3 Acetabular System," that the system included the R3 metal liner component and the femoral head component used in her surgery, and that the system was not approved through the PMA

process (which triggers express preemption) but instead cleared through the 510(k) process. App. Br. at 6. In essence, Plaintiff attempts to argue that even though the R3 metal liner received PMA and even though PMA triggers preemption under *Riegel*, the R3 metal liner is really part of another device that did *not* receive PMA, and therefore the R3 metal liner is *not* entitled to the protection of the express-preemption clause. Indisputable, judicially-noticeable facts demonstrate that her averments not only fail to meet the plausibility standard, they are simply wrong.

Importantly, Plaintiff's Amended Complaint alleges that her injury resulted solely from the "metal-on-metal" interaction between ***the R3 metal liner*** and ***the femoral head component***. *See, e.g.*, A-15 (¶ 30); A-16 (¶ 36). But the R3 Acetabular System cleared in 2007 through the 510(k) process ***did not include either*** the R3 metal liner ***or*** a femoral head component. The FDA approval papers for the R3 Acetabular System, of which the district court properly took judicial notice, A-106 n.2, "nowhere mention [either] an optional metal liner component," A-112, or a femoral head component, A-106. To the contrary, the R3 Acetabular System contained "'liners . . . manufactured from cross-linked polyethylene,'" and "[c]ross-linked polyethylene is not a metal." A-106. And, by definition, an "acetabular" system involves no femoral head component—only components making up the prosthetic *acetabulum*, the hip socket. While a prosthetic femur bone (including the femoral head that interacts with the acetabulum in the hip

joint) is indeed part of a *total* hip replacement surgery, it is not part of the "acetabular" system.[6] Thus, the district court correctly held, after review of the judicially-noticed FDA documents, that the "R3 Acetabular System" cleared by the FDA in 2007 did *not* include *any* device component alleged to have been used in Plaintiff's surgery or alleged to have caused Plaintiff's injury. A-106, A-112-13.

Plaintiff cannot avoid preemption by pleading demonstrably incorrect versions of the regulatory history and demanding that the district court credit her version rather than the FDA's. A court need not accept as true allegations in the complaint that are contradicted by judicially-noticeable facts. *Perry v. NYSARC, Inc.*, 424 F. App'x 23, 25 (2d Cir. 2011); *see also NECA-IBEW Health & Welfare Fund v. Goldman Sachs & Co.*, 693 F.3d 145, 149 n.1 (2d Cir. 2012) (citing *Iqbal*, 556 U.S. at 678–79), *cert. denied*, 133 S. Ct. 1624 (2013); *Hirsch v. Arthur Andersen & Co.*, 72 F.3d 1085, 1095 (2d Cir. 1995) (upholding dismissal where "attenuated allegations" supporting the claim were "contradicted both by more specific allegations in the Complaint and by facts of which [the court] may take judicial notice"). Here, as Judge Engelmayer explained, Plaintiff "describe[d] the R3 Acetabular System in a manner flatly inconsistent with that system as defined

[6] Plaintiff's insistence that the femoral head component was part of the R3 Acetabular System is belied by the FDA documents, and her statement that a femoral head is necessarily part of the "R3 Acetabular System," simply because it is used in a total hip replacement, App. Br. at 8 n.4, is incorrect.

and approved by the FDA." A-112. The two device components Plaintiff alleged caused her injury – the R3 metal liner and the femoral head component – were not part of the R3 Acetabular System cleared in 2007. A-56-62.

Plaintiff therefore significantly mis-states the facts with her repeated assertions that her lawsuit involved "the R3 Acetabular System, including a Smith & Nephew optional metal liner component, or R3 metal liner component, and Smith & Nephew femoral head component." App. Br. at 4, 6. Plaintiff seeks to re-define the term "R3 Acetabular System" in an apparent attempt to change the Court's frame of reference away from the actual two components Plaintiff alleged rubbed together to cause her injury: the PMA-approved R3 metal liner and the femoral head component. Neither of those components was in the R3 Acetabular System cleared by the FDA through the 510(k) process, and that clearance therefore is altogether irrelevant to the preemption issue presented here.

Indeed, even the femoral head component may be irrelevant given the somewhat different theory of liability that Plaintiff's counsel articulated during oral argument on the motion to dismiss. Counsel clearly and repeatedly stated that Plaintiff's theory pertains *only* to the PMA-approved R3 metal liner *itself*—not even to its interaction with the femoral head component. A-90-91; A-126-127.[7]

[7] The theory Plaintiff pleaded in the Amended Complaint related to the R3 metal liner interacting with the femoral head component. *See, e.g.*, A-15 (¶ 30); A-16 (¶ 36). Although Plaintiff has arguably abandoned that theory with her concession

Because the R3 metal liner was approved as safe and effective by the FDA through the rigorous PMA process, and because each of Plaintiff's causes of action attacked the safety and effectiveness of the R3 metal liner, the district court correctly dismissed the Amended Complaint as preempted by federal law.

D. Plaintiff's Physician's Off-Label Use of the R3 Metal Liner Does Not Defeat Preemption.

Plaintiff appears also to assert that the preemption analysis turns on how her particular physician chose to use the PMA-approved R3 metal liner during her surgery. Specifically, Plaintiff appears to argue that even if the R3 metal liner was approved through the PMA process, Plaintiff's claims against Smith & Nephew can survive because Plaintiff's doctor chose to use the PMA-approved device with the R3 Acetabular System, a device cleared via the 510(k) process. App. Br. at 4, 6. Plaintiff insists that preemption must turn not on whether the device has met and passed federal PMA requirements, but on whether state law deems those federal requirements (and the underlying testing and safety review) sufficient to address the particular use that the particular plaintiff encountered. That is not what 21 U.S.C.§ 360k(a) says, that is not what the Supreme Court said in *Riegel*, and that is not a tenable way to apply the MDA's express-preemption clause.

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at the hearing, the district court addressed the theory as pleaded, and so Smith & Nephew does the same here.

The text of the statute does not refer to the preemption of requirements imposed on particular *uses*. Rather, the text expressly preempts any state-law requirement "with respect to a *device*." 21 U.S.C.§ 360k(a). And the text preempts not just requirements that are "different" from the federal requirements, but also "in addition to" the federal requirements, *id.* § 360k(a)(1)—making clear that state law cannot impose its own requirements based on the notion that it is just sweeping more broadly than federal law. Furthermore, the text makes clear that *any* additional or different state-law regulation is preempted if it "relates to the safety or effectiveness of the device," whether or not it also relates to anything "included in a requirement applicable to the device under [the federal MDA]." *Id.* § 360k(a)(2).

The Supreme Court's decision in *Riegel* is also entirely incompatible with any interpretation that would make preemption turn on doctors' and patients' strict adherence to the approved uses. *Riegel* itself dealt with a medical device used in a way that was not just off-label,[8] but *contraindicated* by the labeling. *See* 552 U.S. at 320 (plaintiff's physician used device in a particular manner "although the device's labeling stated that use was contraindicated" for the manner in which it

[8] If, as in Plaintiff's case, a physician decides to use a medical device in a way other than that approved by the FDA, such use is described as "off-label." *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (defining "off-label" use as "use of a device for some other purpose than that for which it has been approved by the FDA").

was used). *Riegel* thus refutes any attempt to focus on the use rather than on the "device," as the statute directs. *See Ledet v. Medtronic, Inc.*, No. 1:13CV200-LG-JMR, 2013 WL 6858858, at *3 (S.D. Miss. Dec. 30, 2013) ("The [device] manufactured by [defendant] is a Class III device that received [PMA] from the FDA. The off-label use of the [component part] of [the device] in the present case does not affect this determination."), *appeal dismissed* (May 21, 2014); *Gavin v. Medtronic, Inc.*, Civ. A. No. 12-0851, 2013 WL 3791612, at *12 (E.D. La. July 19, 2013) (finding plaintiff's off-label use argument "clearly inconsistent with *Riegel* which also involved the off-label use of a medical device"); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1218 (W.D. Okla. 2013) ("Nothing in the [360k] statute suggests that the preemption analysis somehow depends on how the device is used." (internal quotations omitted)), *reconsideration denied* (Apr. 8, 2013); *Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 778-79 (D. Minn. 2009) (considering the *Riegel* Court's preemption finding in the face of off-label use allegations and finding preemption despite off-label use claims); *Cornett v. Johnson & Johnson*, 414 N.J. Super. 365, 395, 998 A.2d 543, 561 (N.J. Super. Ct. App. Div. 2010) (same), *aff'd as modified*, 211 N.J. 362, 48 A.3d 1041 (2012).

More generally, the express-preemption clause would offer little protection to manufacturers if plaintiffs could circumvent it merely by stating a rote allegation about how a physician, or someone else completely independent of the

manufacturer, had used the device. And Plaintiff never justifies the rule she advances—that if a PMA device and a 510(k) device are used together, the PMA device's preemption protection is neutralized. Plaintiff cites no authority for that proposition; to the contrary, the handful of cases she does cite squarely support *Smith & Nephew's* position, because they hold that a PMA-approved component of a larger system can justify protecting the *entire system* from state-law requirements.[9] This Court need not go that far in this case, of course, because Plaintiff's claims focused directly on the R3 metal liner—a PMA-approved device.

Importantly, the United States Supreme Court also has recognized the benefits of a physician, in his or her discretion, using a medical device in a way different from that approved by the FDA. *See Buckman*, 531 U.S. at 350 ("[O]ff-label usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice

[9] For reason that are unclear, Plaintiff discusses three cases that all *sustain* preemption claims: *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648 (S.D. Tex. 2010); and *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466 (D. Mass. 2012). App. Br. at 34-39. Each case held state-law claims as to the PMA-approved device preempted. Only one of them — *Riley* — addressed off-label use and indeed held such a theory did *not* vitiate preemption. 625 F. Supp. 2d at 778-79. Moreover, these cases support the district court's conclusion that claims as to the R3 metal liner and claims as to the femoral head should not be separated for purposes of the preemption analysis, but rather, the claims are wholly preempted. *See infra* section I.F.

of medicine.").[10] Federal law does not contain a requirement precluding off-label use of a device. Accordingly, any state law that imposed liability — simply because a physician, in his or her medical judgment, opted to use a particular device in an off-label manner — would itself be preempted, because the penalty for off-label use imposes requirements "different from, or in addition to" the federal requirements, and would be contrary to the federal regulatory scheme. *See Smith v. Medtronic, Inc.*, Civ. A. No. 13-451, 2014 WL 2547813, at *4 n.3 (W.D. La. June 4, 2014) (reasoning in *Buckman* foreclosed plaintiff's off-label use argument); *see also Bertini*, 2014 WL 1028950, at *3 (citing *Buckman*); *Gavin*, 2013 WL 3791612, at *11(citing *Buckman*). At a minimum, adding an element of off-label use does not *revive* an otherwise-preempted state-law claim. Therefore, Plaintiff's theory fails under *Riegel* and its progeny, and the district court properly rejected it.

E. Plaintiff's Belated Argument That Smith & Nephew Marketed the R3 Metal Liner for Off-Label Use Does Not Save Her Claims from Preemption.

Although it is difficult to parse the various arguments in Plaintiff's brief, a central theme appears to be that Smith & Nephew purportedly "marketed and

[10] Notably, Plaintiff herself agrees in her appellate brief that "[c]ourts have determined that preemption analysis should not be defeated by the 'off label' or 'off market' use of a device or product by a medical professional." App. Br. at 40 (citing *Buckman*).

designed the metal liner as a component of the R3 Acetabular System"[11] and therefore, somehow, the claims as to the R3 metal liner are not preempted. As an initial matter, the district court correctly determined that this theory of liability was not adequately pleaded in Plaintiff's Amended Complaint. A-123. Even *if* Plaintiff *had* alleged this theory of liability in her Amended Complaint, Plaintiff's theory is fatally flawed for multiple reasons.

1. Plaintiff's off-label marketing theory is expressly preempted by federal law.

Alleging not only that doctors made off-label use of the R3 metal liner, but also that Smith & Nephew actually marketed the device for off-label use, still would not defeat express preemption. As noted above, the focus of the preemption clause is on the device, and not on the use of the device, and state-law tort liability is not to be used to police compliance with *federal* requirements.

The Eastern District of New York recently addressed the same theory Plaintiff raises in her appeal. In *Bertini*, a case involving the same R3 metal liner at issue in Plaintiff's dismissed action, the court granted the motion to dismiss all causes of action, with prejudice, on federal preemption and inadequate pleading grounds. 2014 WL 1028950. Although the *Bertini* plaintiffs had admitted that the R3 metal liner was approved via the PMA process for use with the BHR System,

[11] As established *supra* Section I.C, the "R3 Acetabular System" that Plaintiff describes did not include the R3 metal liner.

they had argued, as Plaintiff does here, that Smith & Nephew "nonetheless marketed the R3 metal liner to be used with the R3 System." *Id.* at *6. The *Bertini* court flatly rejected this argument, holding that the "preemption analysis is not concerned with how a particular device is used or whether there are federal requirements imposed on a particular use of the device. Rather, preemption is focused on whether there are federal requirements applicable to the device itself." *Id.* (citing *Riley*, 625 F. Supp. 2d at 779). "That the R3 metal liner was approved for use with the BHR System does not affect defendant's preemption argument under the MDA, since the specific component at issue received PMA." *Id.*; *see also Beavers-Gabriel v. Medtronic, Inc.*, Civ. No. 13-00686 JMS-RLP, 2014 WL 1396582, at *8 (D. Haw. Apr. 10, 2014).

For this same reason, the district court correctly deemed Plaintiff's argument, which she asserted in her motion for reconsideration, "unconvincing on the merits." A-125. "In determining whether claims relating to the safety and effectiveness of an FDA-approved device are preempted by the MDA, the question is not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable to the *device*." A-126 (quoting *Riley*, 625 F. Supp. 2d at 779 (internal quotation marks omitted)) (citing *Bertini*, 2014 WL 1028950, at *6). Because the R3 metal liner, which was a Class III medical device PMA-approved by the FDA, was "at the

heart of each and every one of [Plaintiff's] claims," the district court held correctly that the entire Amended Complaint was preempted by federal law. A-127.

Furthermore, even *if* such allegations were pleaded in the Amended Complaint, they would seek to impose requirements different from or in addition to federal law and would thus be preempted pursuant to *Riegel*. 552 U.S. at 321. Off-label promotion is not an explicit violation of the federal Food, Drug, and Cosmetic Act ("FDCA"). In fact, this Court recently recognized that "[t]he FDCA and its accompanying regulations do not expressly prohibit the 'promotion' or 'marketing' of drugs for off-label use." *United States v. Caronia*, 703 F.3d 149, 154 (2d Cir. 2012)); *accord id.* at 168 ("We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs."); *Schuler v. Medtronic, Inc.*, No. CV 14-00241-R, 2014 WL 988516, at *1 (C.D. Cal. Mar. 12, 2014) ("Further, although Plaintiffs[] aver that Medtronic violated federal law through off-label promotion of its device, Plaintiffs have failed to identify any federal prohibition on such activity. Because federal law does not bar off-label promotion, Medtronic's alleged off-label promotion cannot give rise to a state-law claim that is not preempted." (citing *Caronia*, 703 F.3d at 160 (2d Cir. 2012)).

Still, even *if* Plaintiff had pleaded, or could plead, a violation of a federal prohibition on a manufacturer engaging in off-label promotion, Plaintiff would not

have alleged a violation of federal law that is *specific to the device at issue* in this case, and therefore such a claim would not escape preemption. A-76. Broad federal requirements applicable to all medical devices do not suffice to state a non-preempted state-law claim regarding a PMA-approved medical device. *See, e.g.*, *Franzese*, 2014 WL 2863087, at *4-5; *Burkett*, 2014 WL 1315315, at *5; *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588-89 (E.D.N.Y. 2009); *Kaiser v. Depuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1191-92 (M.D. Fla. 2013).

2. Plaintiff's off-label marketing theory is impliedly preempted by federal law.

Even *if* Plaintiff had pleaded a violation of federal law specific to the device components at issue, Plaintiff's off-label marketing claims would be impliedly preempted by federal law. A-82. Seeking to use *state* law to punish a manufacturer for off-label marketing is precluded, because only the federal government may enforce the FDCA. 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter [*i.e.*, the FDCA] shall be by and in the name of the United States."). The Supreme Court explained in *Buckman* that Congress made clear through § 337 that whether a manufacturer of a medical device complied with regulations is solely a matter of federal concern, and therefore a matter that only the federal government can address. 531 U.S. at 349 n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with the

[law].”). *Buckman* held that only the federal government, not private litigants, can enforce the FDCA. *Id.* Even if the FDCA banned the off-label promotion of a medical device, a private litigant such as Plaintiff would be categorically barred from asserting a claim to enforce the FDCA. Several courts have so held. *See, e.g.*, *Ledet*, 2013 WL 6858858, at * 4 (“To the extent that a plaintiff’s fraud claims are based upon . . . [Medtronic’s] practice of promoting and marketing to physicians the off-label use of the [] Device, the claims are impliedly preempted, because even the concept of ‘off-label’ use is a creature of the FDCA. Therefore, the [plaintiffs’] fraud claims related to off-label use arise solely out of the FDCA, not state substantive law, and are subject to implied preemption.” (internal quotations omitted)); *Gavin*, 2013 WL 3791612, at *11 (holding that off-label promotion claims are impliedly preempted under *Buckman* and 21 U.S.C § 337(a)); *Dawson v. Medtronic, Inc.*, No. 3:13-CV-663-JFA, 2013 WL 4048850, at *6 (D.S.C. Aug. 9, 2013) (finding that FDCA does not bar off-label promotion, but even if it did, such a claim “would be in substance a claim for violating the FDCA and, thus, would be clearly preempted under *Buckman* and § 337 (a).”); *Caplinger*, 921 F. Supp. 2d at 1220 (same).

It bears repeating that, even *if* Plaintiff’s off-label promotion theory somehow could survive both express and implied preemption, the Amended Complaint contained *no* facts whatsoever regarding *any* action on the part of Smith

& Nephew to affect Plaintiff's physician's medical judgment to use the metal liner in Plaintiff's surgery. Accordingly, as discussed in detail in Section II.F *infra*, Plaintiff failed to state a plausible, non-preempted claim for relief.

F. Because the R3 Metal Liner Was at the Heart of Each Claim, the Amended Complaint Was Preempted in Its Entirety.

In the words of the district court, the R3 metal liner was the "gravamen" of each of Plaintiff's claims, A-126,[12] and, therefore, none of Plaintiff's claims could survive the preemption analysis. In her Amended Complaint, Plaintiff alleged that the cause of her injury was the "metal-on-metal" interaction, *see, e.g.*, A-24-25 (¶¶ 62, 63, 65), *i.e.*, the interaction between the PMA-approved R3 metal liner and the femoral head component, A-15 (¶ 30). Plaintiff did not allege that the femoral head component (or the "R3 Acetabular System," as she incorrectly characterizes the other component at issue in this case), alone, was defective, or that that component, alone, caused her injuries. A-126. In fact, each of Plaintiff's causes of action required pleading proximate cause as a necessary element — *see Tuosto v. Phillip Morris USA Inc.*, No. 05 Civ. 9384(PKL), 2007 WL 2398507, at *12

[12] The district court also noted that "when pressed at argument," Plaintiff's counsel backtracked from the allegations in the Amended Complaint and instead "flatly stated that the optional metal liner *itself* was the source of [Plaintiff's] injury," and not the interaction between the PMA-approved R3 metal liner and the femoral head component. A-126. Still, "[w]hether [Plaintiff's] injuries are understood to have resulted from that liner alone (as counsel clarified at argument), or from use of that liner in combination with other components of the R3 Acetabular System (as the Amended Complaint appeared to allege), the metal liner is at the heart of each and every one of [Plaintiff's] claims." A-127.

(S.D.N.Y Aug. 21, 2007) (design defect); *Lewis*, 2009 WL 2231701, at *4 (negligence); *id.* at *6 (breach of implied warranty) — yet, notably, Plaintiff did not plead (and cannot plead) any injury caused by the femoral component alone. The Amended Complaint was devoid of any allegations that the femoral head component (or, as Plaintiff misconstrues it, the "R3 Acetabular System") caused injury to Plaintiff apart from its use with the R3 metal liner. Rather, the claims as to the R3 metal liner and the femoral head component were inextricably intertwined. The district court appropriately concluded that because Plaintiff's state-law claims pertaining to the PMA-approved R3 metal liner were preempted, the claims relating to the off-label use of the liner with the femoral component also were preempted. A-127-28.

In reaching this conclusion, the district court agreed with the recent *Bertini* decision, which had "faced the identical issue" in a case involving the R3 metal liner at issue in the instant appeal. A-127. In *Bertini*, because the plaintiff's injuries were alleged to have been caused by the interaction between two components,[13] the court "appli[ed] a preemption analysis for the hip replacement system as one unit, and [chose to] not examine each individual component." 2014

[13] In *Bertini*, the claims involved the interaction between the R3 metal liner and the R3 acetabular shell. 2014 WL 1028950, at *4. In the instant appeal, Plaintiff's claims involved the interaction between the R3 metal liner and the femoral head component. A-15-16; App. Br. at 7-8.

WL 1028950, at *5. Because the plaintiffs would have been unable to show that the acetabular shell component alone proximately caused Mr. Bertini's purported injuries, and because "the separate components' alleged defects [were] interconnected and [were] claimed to have caused a single failure within the hip replacement system," *id.* at *8, the court decided that "if a claim involving the R3 metal liner's alleged defect is preempted, the entire claim should be dismissed," *id.* at *5.[14] Accordingly, the court held each of the claims, including those for design defect, negligence, and breach of implied warranty, preempted by federal law. This Court should do the same.

II. The District Court Correctly Held That Each Of Plaintiff's Causes Of Action Was Inadequately Pleaded Under Federal Pleading Standards.

A. The Standard of Review.

This Court reviews *de novo* a district court's grant of a motion to dismiss for failure to state a claim upon which relief may be granted. *See, e.g., Gander Mtn. Co. v. Islip U-Slip LLC*, No. 13-0912-CV, 2014 WL 1284842, at *1 (2d Cir. Apr. 1, 2014).

[14] As discussed *supra* note 9, it is unclear why Plaintiff extensively relies on *Lewkut*, *Duggan*, and *Riley* in her brief, when these cases support the district court's decision to consider her claims as to both the R3 metal liner and any other components preempted. *See Gavin*, 2013 WL 3791612, at *11 & n.120 (citing *Lewkut*, *Duggan*, and *Riley* as "persuasive authority" for not separating component parts of a device during the preemption analysis).

B. The *Twombly*/*Iqbal* Pleading Standard.

In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the United States Supreme Court expressly articulated the federal pleading standard applicable to Plaintiff's Amended Complaint. For a complaint to survive a Rule 12(b)(6) motion to dismiss, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. Under the *Twombly* standard, a plaintiff must allege "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence" of the purported claims. *Id.* at 556. A proper pleading "requires more than labels and conclusions." *Id.* at 555. The "threshold requirement of Rule 8(a)(2)" is that the complaint "possess enough heft to show that the pleader is entitled to relief." *Id.* at 557 (internal quotation marks omitted). A plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570; *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 347 F. App'x 617, 619 (2d Cir. 2009) (quoting *Twombly*, 550 U.S. at 570). Unless a plaintiff "nudge[s] [her] claims across the line from conceivable to plausible, [her] complaint must be dismissed." *Twombly*, 550 U.S. at 570; *see also Panther Partners*, 347 F. App'x at 619 (quoting *Twombly*, 550 U.S. at 570).

In *Iqbal*, the Supreme Court established a two-step process based on Federal Rule of Civil Procedure 8(a) for determining whether a complaint meets the

standard to survive a motion to dismiss. 556 U.S. at 680-81. First, the court must identify those allegations that, because they are no more than conclusions, are not entitled to the assumption of truth. *See id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," *id.* at 678 (citing *Twombly*, 550 U.S. at 555), nor do "[f]ormulaic recitation[s] of the elements of [the] cause[s] of action" with no facts to support the claims, *Twombly*, 550 U.S. at 555; *Iqbal*, 556 U.S. at 678. "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. Complaints comprised of "'naked assertion[s]' devoid of 'further factual enhancement'" are plainly insufficient. *Id.* at 678 (quoting *Twombly*, 550 U.S. at 557).

Second, the court should assume the truth of well-pleaded factual allegations, if the complaint contains any, and determine whether they plausibly give rise to an entitlement to relief. *See id.* at 681. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but has not 'show[n]' – 'that the pleader is entitled to relief,'" and it, therefore, should be dismissed. *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)). The Rule 8 pleading standard requires "more than an unadorned, the defendant-unlawfully-harmed-me accusation." *Id.* at 678 (citing *Twombly*, 550

U.S. at 555). Courts must dismiss claims that assert only "a sheer possibility that a defendant has acted unlawfully." *Id.*

Plaintiff misunderstands the pleading standard articulated in *Twombly* and *Iqbal*, including what it means to plead *facts* in support of the elements of her causes of action. Instead, Plaintiff repeatedly states in her brief that her claims should have survived because Smith & Nephew was on "notice" of the claims against it. App. Br. at 5-6; 23. However, following *Twombly* and *Iqbal*, mere notice pleading no longer suffices in federal court. *See Sikhs for Justice v. Gandhi*, No. 13 Civ. 4920(BMC), 2014 WL 2573487, at *5 (E.D.N.Y. June 9, 2014) (rejecting plaintiff's argument that "[u]nder notice pleading, plaintiff may plead conclusions, so long as the conclusions provide defendant with minimal notice of the claim"). Plaintiff failed to plead *facts* in support of her causes of action, and her brief's rehashing of her inadequately-pleaded allegations does not warrant reversal of the district court's dismissal.[15]

[15] Plaintiff asserts that a lower pleading standard applies because she has not had the opportunity to conduct discovery, relying on the Seventh Circuit's ruling in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010). App. Br. at 15. *Bausch* is not binding on this Court, and its reasoning has been rejected by several courts, including the Eighth Circuit in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1207 (8th Cir. 2010), and the Eastern District of New York in *Bertini v. Smith & Nephew, Inc.*, No. 13 CIV. 0079(BMC), 2013 WL 6332684, at *4 (E.D.N.Y. July 15, 2013) (finding reliance on *Bausch* "not compelling"); *see Ali v. Allergan USA, Inc.*, No. 1:12-cv-115 (GBL/TRJ), 2012 WL 3692396, at *14 (E.D. Va. Aug. 23, 2012) ("This is precisely the sort of fishing expedition the Supreme Court sought to avoid in requiring the plaintiff to

C. Plaintiff Did Not Allege Sufficient Facts to Support Her Design Defect Cause of Action.

Plaintiff concedes that the elements of a design defect cause of action under New York law are: "'(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury.'" App. Br. at 17 (quoting *Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001)). However, she then spends nearly six pages unwittingly highlighting that her Amended Complaint lacked concrete facts to support these elements. App. Br. at 18-23. She merely rehashes the conclusory statements in her Amended Complaint that lacked sufficient factual support pursuant to the federal pleading standard articulated in *Twombly* and *Iqbal*.

Plaintiff's design defect cause of action was inadequately pleaded under New York law for at least two reasons. First, Plaintiff failed to allege adequately any particular defect in the *design* of the R3 metal liner or the femoral head component that purportedly caused her injuries. *See, e.g.*, *Goldin v. Smith & Nephew, Inc.*, No. 12 Civ. 9217(JPO), 2013 WL 1759575, at *4 (S.D.N.Y. Apr. 24,

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plead facts demonstrating their entitlement to relief and the defendant's liability for misconduct. . . . '[A] district court must retain power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.' Plaintiffs cannot be permitted to pursue 'extensive discovery' with nothing more than a series of conclusory allegations and an unfounded hope that the process will yield favorable facts." (internal citations omitted)).

2013) (dismissing design defect claim where plaintiff "[did] not identify any particular problem in the design of the product"). Second, Plaintiff failed to plead adequately that a feasible alternative design existed. *See, e.g., id.*

1. Plaintiff failed to plead facts in support of a defect in the design of the device.

In her Amended Complaint, Plaintiff attempted to identify the so-called design defect of the device components by merely re-stating what she alleged was the safety risk associated with the interaction between the R3 metal liner and the femoral head component:

> [T]he R3 Acetabular System and relevant components as designed, posed a substantial likelihood of harm, specifically, its propensity to deteriorate prematurely and release cobalt and chromium into the human body, the propensity of the metal on metal components to grind against each other and create metal debris and the corrosion of the device, the propensity that metal particles will cause damage to the bone, muscle and nerves, that the metal components can slide against each other while running and/or walking causing friction and the release of metal particles into the bloodstream and human body . . . .

A-24 (¶ 62). Avoiding pleading an actual problem or defect in the *design* of the components, Plaintiff "merely pleaded the legal conclusion that the [products were] defective." *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012). She did not plead facts identifying an existing design defect.

Allegations, like Plaintiff's, that the product was inherently dangerous because it caused various side effects are conclusory and therefore must be dismissed. *Lewis*, 2009 WL 2231701, at *4; *see also Bertini*, 2013 WL 6332684, at *2 (allegations that "defendant's R3 liner 'loosened;' that the FDA found the R3 liner to be 'adulterated,' and that defendant recalled the R3 liner due to problems with loosening, among other issues" were "not sufficient to plausibly show that the device was defectively designed"); *Goldin*, 2013 WL 1759575, at *4 (dismissing design defect claim where plaintiff "[did] not identify any particular problem in the design of the product"); *Am. Guarantee & Liab. Ins. Co. v. Cirrus Design Corp.*, No. 09 Civ. 8357 (BSJ)(HBP), 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010) ("Plaintiffs do not specify a particular design defect . . . . Plaintiffs do not offer sufficiently detailed facts that would allow a reasonable person to conclude that the product should not have been marketed in its present form.").

Judge Engelmayer properly dismissed Plaintiff's design defect claim, as Plaintiff merely alleged that the device components included an increased risk of problems associated with metal debris and concluded they were defectively designed. A-113. These conclusory allegations failed to identify how the device components purportedly were designed defectively.[16] *Id.* Plaintiff pleaded nothing

[16] Plaintiff argues that her allegation as to the voluntary market withdrawal of the R3 metal liner supported her design defect claim. App. Br. at 19-20, 22. But as numerous federal courts have recognized, the "bare fact of the voluntary recall

more than "unadorned, the defendant-unlawfully-harmed-me accusation[s]" and her claims therefore were properly dismissed. *See Iqbal*, 556 U.S. at 678; *Bertini*, 2013 WL 6332684, at *3 ("A design defect claim is subject to dismissal where plaintiff fails to plead facts identifying how the device is defectively designed[.]").

In fact, Plaintiff's appellate brief underscores the insufficiency of the Amended Complaint's allegations. She merely argues that she pleaded "specific injuries and side effects" and the "propensity" of the device to "cause injury." App. Br. at 20. These allegations do not pass muster. *See, e.g.*, *Goldin*, 2013 WL 1759575, at *4 (allegations that "product poses a risk of harm because of its propensity to dislocate" insufficient without "identify[ing] any particular problem in the design of the product"). Despite being made aware of New York case law cited by Smith & Nephew and by the district court, Plaintiff appeals the district

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does not suffice to prove a design defect." *Goldin*, 2013 WL 1759575, at *4 (allegation of voluntary recall, absent any facts demonstrating that the product as designed posed a substantial likelihood of harm, is insufficient to state a design defect claim); *see Bertini*, 2013 WL 6332684, at *3 ("[M]erely alleging that the device was recalled due to [the] performance issue does not suffice to plausibly show that the device itself is defective."); *cf. Ali*, 2012 WL 3692396, at *12 (finding insufficient plaintiff's recall allegation where plaintiff did not allege recall of same model used in plaintiff's surgery or that product was recalled for defect that caused plaintiff's injury). Plaintiff failed to plead facts sufficient to link the voluntary market withdrawal to any alleged defect in the *design* of the device. Plaintiff's allegation of the voluntary withdrawal failed to "nudge [her] claim[] across the line from conceivable to plausible," *Twombly*, 550 U.S. at 570, and the district court properly held that it did not adequately support Plaintiff's cause of action.

court's decision simply by re-quoting the insufficient allegations in the Amended Complaint, with no attempt to distinguish or challenge the ample case law that defeats her position. App. Br. at 20-23. Simply put, the inadequate allegations did not amount to *facts* showing a design defect, and the district court correctly dismissed the cause of action.

2. Plaintiff failed to plead facts in support of the existence of a feasible alternative design.

Additionally, Plaintiff failed to allege that a feasible alternative design existed for the device components at issue, as is required to establish a design defect claim under New York law. *See Bertini*, 2013 WL 6332684, at *3; *Goldin*, 2013 WL 1759575, at *4; *Reed*, 839 F. Supp. 2d at 578. New York federal courts readily dismiss design defect claims for failure to allege adequately a feasible alternative design. *See, e.g.*, *Bertini*, 2013 WL 6332684, at *4 (dismissing design defect claim where "[p]laintiffs fail[ed] to plead any facts to plausibly suggest that it was feasible to design the R3 liner used in their case in a safer manner"); *Goldin*, 2013 WL 1759575, at *4 (dismissing design defect claim because plaintiff failed to plead "that it was feasible to design the product in a safer manner that would have prevented [p]laintiff's injuries"); *Reed*, 839 F. Supp. 2d at 578 (dismissing design defect claim because "[p]laintiffs d[id] not plead facts alleging the existence of a feasible alternative design that would make the product safer"); *Am. Guarantee*, 2010 WL 5480775, at *3 (dismissing design defect claim because plaintiffs did not

"make any mention of a feasible alternative design"); *Lewis*, 2009 WL 2231701, at *4 (dismissing design defect claim because "plaintiff has not alleged that it was feasible for [defendant] to design [the product] in a safer manner").

Plaintiff attempted to meet her pleading requirement by alleging that *other* hip device manufacturers designed non-"metal-on-metal" devices. A-24 (¶ 62). She also argues in her brief that Smith & Nephew manufactured non-"metal-on-metal" devices as well. App. Br. at 22. As numerous courts have held, such pleadings are insufficient. *See, e.g.*, *Bertini*, 2013 WL 6332684, at *4 ("It is not enough for plaintiffs to allege that defendant's device poses risks that are 'unreasonably greater than other similar products' and that defendant sold other versions of the R3 liner that were less dangerous than the one used in plaintiff's surgery. Not only are these allegations merely conclusory, but they fail to provide any facts as to specific products that have a safer design or whether it would have been feasible for defendant to design this particular R3 in a safer manner. In other words, simply alleging that there were 'safer' R3 liners in defendant's possession does not mean that the R3 implanted in plaintiff could have been designed in a safer manner. There is no way to tell whether other R3 liners would have even been appropriate for implantation in plaintiff."); *see also Goldin*, 2013 WL 1759575, at *4; *Salvio v. Amgen, Inc.*, No. 2:11-cv-00553, 2012 WL 517446, at *7 (W.D. Pa. Feb. 15, 2012) ("[A] number of federal district courts . . . have held that

'an alternative design must not be an altogether essentially different product.'" (citing cases)). Accordingly, the district court correctly held that a vague allegation that a different product could have been used in Plaintiff's surgery is not sufficient to support the existence of a reasonable alternative design. A-114 ("[A]n allegation that Smith & Nephew could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of a design defect."). Notably, Plaintiff repeats this argument she made in the lower court without addressing, in any way, the New York federal case law cited against her argument in the district court proceedings. *See* App. Br. at 21-23.

Plaintiff failed to plead adequately under New York law that any feasible alternative design existed for the device components that purportedly caused her injury. Accordingly, the district court correctly held that plaintiff failed to plead adequate facts in support of her design defect claim, and, therefore, properly dismissed this cause of action.

D. Plaintiff Did Not Allege Sufficient Facts to Support Her Negligence Cause of Action.

Plaintiff's Amended Complaint failed to allege sufficient facts to support her purported negligence cause of action. Under New York law, the elements of a negligence claim are: (1) the manufacturer owed plaintiff a duty to exercise reasonable care; (2) the manufacturer breached that duty rendering the product *defective*; (3) the *defect* proximately caused the plaintiff's injury; and (4) the

plaintiff was injured. *Lewis*, 2009 WL 2231701, at *4 (emphases added). The district court correctly found that Plaintiff's purported negligence claim centered around her design defect theory of liability. A-116. And, as established *supra*, Plaintiff failed to plead adequately a claim for design defect.

Even if this Court entertained the notion that Plaintiff's negligence claim was based on some theory of liability other than design defect, the Amended Complaint merely contained a laundry list of boilerplate language in an attempt to establish a negligence claim, but with no specific facts indicating how Smith & Nephew allegedly breached any duty of ordinary care. A-19-20 (¶¶ 49-50). These conclusory allegations without factual support did not suffice to state a claim for negligence.[17] The district court properly held that the Amended Complaint merely

[17] Recently, two New York federal courts, reviewing similar allegations in hip replacement cases, have found that plaintiffs' boilerplate negligence allegations, with no factual support for how Smith & Nephew allegedly breached its duty of care, failed under the *Twombly*/*Iqbal* pleading standard. *See, e.g.*, *Bertini*, 2013 WL 6332684, at *5 ("[P]laintiffs list ten different ways in which defendants allegedly breached their duty of reasonable care, such as the following: 'fail[ing] to conduct adequate post marketing surveillance,' 'failing to make timely and adequate corrections to the manufacture, design and formulation of R3 liner so as to prevent and/or minimize the problems suffered by R3 liner use,' and 'despite its knowledge [the product's risks], . . . continu[ing] to promote and market the R3 liner.' These are boilerplate allegations from some form book. Plaintiffs fail to support them with any facts. The negligence claim too must therefore be dismissed."); *Goldin*, 2013 WL 1759575, at *6 (dismissing negligence claim where "Plaintiff allege[d] that Smith & Nephew knew or should have known about the risks associated with the R3 Constrained Acetabular Liner . . . , but [did] not offer factual allegations to support this legal conclusion."). Here, Plaintiffs' allegations

contained "rote incantations of the elements" in support of her negligence claim, but did "not contain any concrete factual allegations to back up these legal conclusions." A-117.[18]

E. Plaintiff Did Not Allege Sufficient Facts to Support Her Breach of Implied Warranty Cause of Action.

Plaintiff's Amended Complaint failed to allege sufficient facts to support her purported breach of implied warranty cause of action. To establish a breach of implied warranty claim under New York law, a plaintiff must prove: "'(1) that the product was *defectively* designed or manufactured; (2) that the *defect* existed when the manufacturer delivered it to the purchaser or user; and (3) that the *defect* is the

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were strikingly similar to those in *Bertini* and *Goldin*, offering nothing beyond a "sheer possibility" that Smith & Nephew breached any duty of reasonable care.

[18] Plaintiff advances a new argument in her brief that Smith & Nephew should be held liable because the R3 metal liner was not tested to assure its safety and effectiveness in a total hip replacement system before it was used in Plaintiff's surgery. App. Br. at 40. However, to be sure, this theory of liability does not appear in the Amended Complaint. Each mention of "testing" in the Amended Complaint was part of a string of other boilerplate, conclusory allegations. *See* A-12 (¶ 3); A-13 (¶ 9); A-19 (¶ 49); A-20 (¶ 50); A-21 (¶ 52); A-23 (¶ 59). Furthermore, Plaintiff pleaded no facts whatsoever showing how this purported failure to test could have caused her injuries. Finally, a negligence claim requires adequate pleading of a defect in the device, which Plaintiff failed to do. *See Goldin*, 2013 WL 1759575, at *6 (dismissing negligence claim where plaintiff "failed to allege sufficient facts in support of her allegation that the R3 Constrained Acetabular Liner was, in fact, defective"). Regardless, as explained *supra* Section I, such a claim would be preempted by federal law, and how the physician chose to use the device in Plaintiff's surgery does not affect the preemption analysis, *see supra* Section I.D. Plaintiff attempts to impose a requirement for the R3 metal liner that the FDA did not.

proximate cause of the accident.'" *Lewis*, 2009 WL 2231701, at *6 (emphases added) (quoting *In re Am. Export Lines, Inc.*, 620 F. Supp. 490, 518 (S.D.N.Y. 1985)). The plaintiff must show that the product is "not fit for the ordinary purpose for which it is to be used." *Id.* (internal quotation marks omitted). The district court properly determined that Plaintiff's breach of implied warranty claim was based on an alleged design defect, which was the only type of defect Plaintiff attempted to plead in her Amended Complaint. However, as the district court concluded, A-113, and as established *supra* Section II.C.1, Plaintiff utterly failed to factually support her claim that the device components were in any way defective.[19] This failure immediately doomed Plaintiff's breach of implied warranty claim under New York law, as the elements of breach of implied warranty are based on showing a defective product. *See Bertini*, 2014 WL 1028950, at *12 (dismissing breach of implied warranty claim where plaintiffs failed to adequately allege a product defect); *Goldin*, 2013 WL 1759575, at *5 (same); *Lewis*, 2009 WL 2231701, at *6 (same); *Reed*, 839 F. Supp. 2d at 578-80 (same). Furthermore, Plaintiff only included boilerplate language setting forth the elements of the breach of implied warranty claim with absolutely no supporting

[19] The district court also ruled that, "[t]o the extent that the Amended Complaint implies that the inclusion of an optional metal liner in [the R3 Acetabular System] rendered it defective, that claim is defeated by the fact that the R3 Acetabular System, as reviewed and approved by the FDA, did not contain any such liner." A-118.

facts. A-28-29 (¶¶ 79-87). She simply reasserted that the device components were "unsafe, unreasonably dangerous, and improper, not of merchantable quality and otherwise defective," A-28 (¶ 83), and that Plaintiff developed her purported injuries as a result of Smith & Nephew's alleged breach, without any supporting factual allegations, A-29 (¶ 88). Because Plaintiff pleaded no facts to support her conclusory allegations, her breach of implied warranty claim was rightfully dismissed. *See Bertini*, 2013 WL 6332684, at *5 ("[P]laintiffs fail to provide any facts demonstrating that the R3 liner was not fit for its ordinary purposes . . . ."); *Reed*, 839 F. Supp. 2d at 580 ("[P]laintiffs have not pled facts making it plausible that [the product] was not fit for its intended purpose.").

F. Plaintiff Did Not Plead Adequately That Smith & Nephew Designed or Marketed the Device for Off-Label Use.

As discussed *supra* Section I.E, permeating Plaintiff's brief is what appears to be a longwinded attempt to resurrect the underlying lawsuit by arguing that Smith & Nephew took some action to affect Plaintiff's physician's medical judgment to utilize the R3 metal liner "off-label" in Plaintiff's surgery. Presumably, Plaintiff's baseless theory, which does not appear in the Amended Complaint, challenges the district court's rulings that she "[did] not allege that Smith & Nephew took any act to design an R3 Acetabular System to contain an optional metal liner component," nor did she allege "that Smith & Nephew encouraged medical personnel to use the optional metal liner component from the

BHR System in conjunction with the R3 Acetabular System." A-112-13. Plaintiff's convoluted argument is rife with flaws, any one of which could serve as the basis for this Court to affirm the district court's decision.

Plaintiff appears to assert in her brief that the Amended Complaint's solitary allegation that Smith & Nephew "introduced a metal liner option for the R3 Acetabular System," A-15 (¶ 26), is actually a claim that Smith & Nephew defectively designed or marketed the R3 metal liner for off-label use. First, as explained *supra* Section I.C, judicially-noticeable documents establish that neither of the device components alleged to have caused Plaintiff's injury — the R3 metal liner and the femoral head component — was part of the "R3 Acetabular System."

Furthermore, to the extent Plaintiff's argument is that the Amended Complaint contained an allegation that Smith & Nephew defectively designed or marketed the R3 metal liner to be used in an off-label manner, any such allegation was wholly conclusory and did not approach the level of plausibility. To adequately plead a theory that Smith & Nephew defectively designed or marketed the R3 metal liner to be used with the femoral head component, Plaintiff's Amended Complaint had to "contain facts plausibly showing that [Smith & Nephew] took some action or actions to market or promote the off-label use of the [device]." *Smith*, 2014 WL 2547813, at *6. Plaintiff came nowhere near reaching her pleading burden in the Amended Complaint. *See, e.g.*, *id.* (holding that a

single factual allegation that defendant paid doctors to write articles downplaying the dangers of the device, even if accepted as true, did not "nudge" plaintiff's claim "across the line from conceivable to plausible" (quoting *Iqbal*, 556 U.S. at 683)). The district court properly rejected Plaintiff's argument in denying Plaintiff's motion for reconsideration, holding that "the use of this one spare verb ['introduced'] does not constitute an explicit allegation that Smith & Nephew marketed the metal liner component that had been approved in connection with the BHR System for use with the separate R3 Acetabular System." A-125. In denying reconsideration, the district court confirmed its original holding that "the Amended Complaint lack[ed] allegations concretely stating that Smith & Nephew designed or marketed the R3 Acetabular System so as to contemplate or encourage use of the metal liner." *Id.*[20]

Furthermore, even if this Court allowed Plaintiff to skate by on this conclusory allegation, each of Plaintiff's causes of action in the Amended Complaint required supporting facts to show how an action on behalf of Smith & Nephew proximately caused Plaintiff's injury. *See supra* Section I.F. But Plaintiff has never asserted how — even if Smith & Nephew designed or marketed the R3

[20] Even *if* the Amended Complaint *had* alleged that Smith & Nephew designed or marketed the R3 metal liner and the femoral head component to be used together, as established *supra* Section I.E, the district court correctly held that the claim still would have been preempted. A-126.

metal liner to be used with the femoral head component during her surgery — such action caused her injury. The Amended Complaint was "wholly void of a description of the actions [Smith & Nephew] took to promote or market the [R3 metal liner] in an off-label manner to her doctor, as well as information linking those actions to her injuries." *See Smith*, 2014 WL 2547813, at *6.[21] Nowhere — not in the Amended Complaint, her written or oral opposition to the motion to dismiss, her briefs in support of her motion for reconsideration, or her appellate brief — has Plaintiff articulated how any hypothetical off-label design or marketing could have proximately caused her injury. Accordingly, Plaintiff has failed to plead, or to establish that she possibly could plead, that Smith &

[21] Perplexingly, Plaintiff attempts in her appellate brief to establish liability by distinguishing between the R3 Acetabular System as a total hip replacement system and the BHR system as a hip resurfacing system. App. Br. at 12-13, 39-40. As described *supra* Section I.C, Plaintiff's injury allegations are related solely to the "metal-on-metal" interaction between the liner and the femoral head. But the BHR system itself is a "metal-on-metal" system, so a metal-on-metal interaction would have occurred even if the R3 metal liner had been used with the BHR system, *i.e.*, "on-label." *See BHR System Overview*, FDA, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078189.htm (last visited July 17, 2014). Indeed, when Judge Engelmayer inquired about this very causation issue, Plaintiff's counsel offered nothing responsive. *See* A-94.

Nephew's purported design or marketing of the R3 metal liner in an off-label manner caused her injury.[22]

[22] In the "Statement of Facts" section of her appellate brief, Plaintiff mentions a press release, App. Br. at 12, presumably in support of her theory that Smith & Nephew designed or marketed the "R3 Acetabular System" to include the R3 metal liner. As a preliminary matter, Plaintiff did not mention this press release in her successive complaints, her written or oral opposition to the motion to dismiss, or even her opening brief in support of her motion for reconsideration. Rather, she improperly submitted it for the first time as an exhibit to her reply in support of her motion for reconsideration. *See* Dkt. 50. Tellingly, the district court did not even address it in its opinion denying the motion for reconsideration. *See* A-120-30. Regardless, Plaintiff has not asserted anywhere that she or her physician even read or relied on the press release in choosing the components for Plaintiff's surgery. In fact, the *Bertini* court recently dismissed the plaintiffs' claims purportedly based on the same press release because the plaintiffs had failed to plead adequately that they or the physician had actually read or relied upon the press release. *Bertini*, 2014 WL 1028950, at *10-11. Furthermore, the press release plainly discloses the correct regulatory status of the R3 metal liner. *See* Dkt. 29, Ex. A ("The metal liner was recently approved by the Food and Drug Administration for use with the BIRMINGHAM HIP ™ Resurfacing (BHR™) System."). Finally, the press release does not advocate the R3 metal liner's use with the femoral head component used in Plaintiff's surgery. Plaintiff's reliance on the term "R3 Acetabular System," with no regard for the component parts contained in that system, continues to be misplaced and misleading. As the district court recognized, Plaintiff's "metal-on-metal" allegations of injury involve the R3 metal liner's interaction with the femoral head component. A-126. The press release does not even mention a femoral head component. Accordingly, for all of the foregoing reasons, Plaintiff's misunderstood reliance on the existence of a press release does not save her Amended Complaint from dismissal.

Plaintiff asserts another flawed argument: that "Smith & Nephew later acknowledges in their own recall notice that it introduced, marketed and designed the metal liner as a component of the R3 Acetabular System." App. Br. at 17. This argument is flawed for a number of reasons, including (1) it was not pleaded in Plaintiff's Amended Complaint; (2) the voluntary market withdrawal notification does not "acknowledge" that "it introduced, marketed and designed the metal liner as a component of the R3 Acetabular System," A-65; (3) as explained

III. The District Court Correctly Denied Plaintiff's Request For Leave To Further Amend Her Complaint.

A. The Standard of Review.

As Plaintiff states, denial of leave to amend is reviewed only for abuse of discretion. *See Hutchison v. Deutsche Bank Sec. Inc.*, 647 F.3d 479, 490 (2d Cir. 2011).

B. Further Amendment Would Be Futile.

The district court appropriately denied Plaintiff leave to amend. A-129. While courts "should freely give leave when justice so requires," Fed. R .Civ. P. 15(a)(2), "it is within the sound discretion of the district court to grant or deny leave to amend," for various reasons including futility, *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007). Plaintiff has not submitted a proposed amendment, but rather describes her proposed amendment only in vague terms, App. Br. at 42-43—which itself is a sufficient basis to affirm the denial of leave to amend again, *see Horoshko v. Citibank, N.A.*, 373 F.3d 248, 249 (2d Cir. 2004) (per curiam) (leave to amend unwarranted without "some indication as to what appellant[] might add to [her] complaint in order to make it viable" (internal

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supra Section I.C, the femoral head component alleged to have caused Plaintiff's injury along with the R3 metal liner was not part of the "R3 Acetabular System"; and (4) Plaintiff has not explained how any purported design or marketing could have caused her injuries, *supra* Section I.F. The district court properly held that "[a]t best, the Amended Complaint can be read to make the conclusory statement that, in some unknown and unexplained manner, Smith & Nephew caused the metal liner to be used with that separate system." A-125.

citations and quotation marks omitted)). But even as loosely sketched by Plaintiff in her brief, the request to amend again was properly denied as futile. Plaintiff's request to amend is largely bound up with the merits: she gives no basis to think that, if the district court's dismissal ruling was correct, she can nonetheless plead a viable claim.

Because each of Plaintiff's causes of action was preempted by federal law irrespective of the proposed amendment, the district court properly denied as futile Plaintiff's request to replead once more. As established above, even if Plaintiff were allowed to amend once again to plead that Smith & Nephew engaged in off-label marketing, that Plaintiff or her physician read and relied on Smith & Nephew's marketing, and that the resulting off-label use proximately caused her injury, such a theory of liability still would be expressly preempted by federal law because it would still seek to impose different requirements under state law than those imposed "with respect to [the] device" as part of the PMA process. The preemption analysis concerns the *approval*, not the use, of the device. *See supra* Sections I.D-E. Furthermore, Plaintiff's proposed amendment would be impliedly preempted. *See supra id.* Accordingly, the district court correctly concluded that such an amendment would be futile. A-129.

Furthermore, it would have been futile to allow Plaintiff to file a second amended pleading because Plaintiff failed to show how she could correct her

various pleading deficiencies. Plaintiff filed her amended complaint after having received and reviewed Smith & Nephew's motion to dismiss Plaintiff's *original* complaint. Dkt. 15. Even though that motion put Plaintiff fully on notice of her various pleading deficiencies, and even though the district court expressly cautioned that "[n]o further opportunities to amend will be granted," Dkt. 18, she failed to cure those deficiencies in the Amended Complaint. It is evident that further amendment would be futile. *See City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 188 (2d Cir. 2014) (upholding denial of leave to amend) ("Plaintiffs have already had one opportunity to amend their complaint. Although that amendment was not in response to a motion to dismiss identifying particular deficiencies in the pleadings, it is unlikely that the deficiencies raised with respect to the Amended Complaint were unforeseen by plaintiffs when they amended.").[23]

Plaintiff argues an amendment "would allow her to amplify factual allegations to the extent deemed necessary by the Court," App. Br. at 42, but she has failed, over the course of more than one year, to indicate any facts that would amount to an adequately pleaded, non-preempted claim for relief. Accordingly,

[23] Plaintiff's appellate brief does not address the district court's denial of her belated request, in her motion for reconsideration, Dkt. 41, for discovery prior to adequately pleading a claim. Any appeal from that decision is therefore waived.

the Court should affirm the district court's decision to deny the "too-little, too-late" request for another amended pleading.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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Dated: July 18, 2014

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because the brief contains 13,804 words, as counted by Microsoft Office Word 2010, excluding the cover, corporate disclosure statement, table of contents, table of authorities, signature block, and certificates of counsel.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in 14 point Times New Roman font, a proportionally spaced typeface, using Microsoft Office Word 2010.

Dated: July 18, 2014

/s/ Glenn S. Kerner
Glenn S. Kerner

CERTIFICATE OF FILING AND SERVICE

I certify that on July 18, 2014, I caused the foregoing Brief of Defendant-Appellee Smith & Nephew, Inc. to be (i) transmitted to the Clerk of the United States Court of Appeals for the Second Circuit through the Court's CM/ECF filing system, and (ii) served on the counsel listed below, who are Filing Users, through the CM/ECF system:

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